SYNOPSIS

Name of Sponsor/Company	Daiichi Sankyo Co., Ltd.
Name of Finished Product	Adsorbed cell culture-derived H5N1 influenza virus vaccine 30μg/mL intramuscular injection “Kitasato Daiichi Sankyo”
Name of Active Ingredient	Inactivated influenza vaccine
Title of Study	Clinical trial of KIB-PCI in healthy pediatric Japanese volunteers
Investigators	－
Study Centre(s)	1 site
Publication (reference)	None
Studied Period	－
Phase of Development	Phase 2
Objectives	To examine the safety and immunogenicity of two different doses of KIB-PCI in healthy pediatric Japanese volunteers
Methodology	A single center, non-randomized, open-label study
Number of Patients (planned and analyzed)	Planned: 30 subjects (7 years to 12 years old: 15 subjects, 13 years to 19 years old: 15 subjects) Enrolled: 30 subjects (7 years to 12 years old: 15 subjects, 13 years to 19 years old: 15 subjects) Analyzed (Safety): 30 subjects (7 years to 12 years old: 15 subjects, 13 years to 19 years old: 15 subjects) Analyzed (Immunogenicity): 30 subjects (7 years to 12 years old: 15 subjects, 13 years to 19 years old: 15 subjects)
Diagnosis and Main Criteria for Inclusion	Diagnosis: Healthy Japanese pediatric volunteers Inclusion: 1) An age range from 7 years to 19 years old at the time of obtaining informed consents 2) A subject without any health problems to participate in the study, judged by investigators or sub-investigators 3) Able to comply with all trial procedures, take examinations stipulated in the protocol, and report their symptoms (report from legal representatives is also acceptable)
Test Product, Dose and Mode of Administration, Batch Number	Test product (batch number): KIB-PCI 30 μg/mL formulation (CR-PCI-012) Dosage and administration: For subjects aged 7 years to 12 years old, two-dose intramuscular administration of KIB-PCI (0.1 mL) at 3 μg (as HA content) For subjects aged 13 years to 19 years old, two-dose intramuscular administration of KIB-PCI (0.25 mL) at 7.5 μg (as HA content) Each vaccination (14-28 days apart) was administered in the deltoid region on opposite sides of the body.
Duration of Treatment	6 weeks
Reference Therapy, Dose and Mode of Administration,	None

Batch Number	
Criteria for Evaluation	Primary endpoint: SRH antibody titer Secondary endpoint: HI antibody titer Neutralizing antibody titer
Statistical Method	The following analyses were carried out in each age group 1) Seroconversion rate For SRH antibody titer, the seroconversion rates with their 95% confidence intervals (95% CIs) were calculated at approximately 3 weeks after each vaccination. 2) Geometric Mean Titer Ratio (GMTR) For SRH antibody titer, GMTRs with their 95% CIs on the basis of geometric mean titer (GMT) before the 1st vaccination were calculated at approximately 3 weeks after each vaccination. 3) Seroprotection rate For SRH antibody titer, the seroprotection rates with their 95% CIs were calculated at approximately 3 weeks after each vaccination.
Summary - Conclusion	Immunogenicity summary: The seroconversion rate (95% CI) in SRH antibody titer approximately 3 weeks after the 2nd vaccination was 80.00% (51.91 to 95.67) in the 7 year to 12 year age group and 46.67% (21.27 to 73.41) in the 13 year to 19 year age group. The GMTR of SRH antibody titer (95% CI) approximately 3 weeks after the 2nd vaccination was 5.356 (3.456 to 8.301) in the 7 year to 12 year age group and 3.333 (1.941 to 5.724) in the 13 year to 19 year age group. The seroprotection rate (95% CI) in SRH antibody titer approximately 3 weeks after the 2nd vaccination was 80.00% (51.91 to 95.67) in the 7 year to 12 year age group and 46.67% (21.27 to 73.41) in the 13 year to 19 year age group. Safety summary: The incidence of adverse events was 73.3% (11/15) in the 7 year to 12 year age group and 86.7% (13/15) in the 13 year to 19 year age group. The most frequently reported adverse events were injection site pain (33.3% [5/15] in the 7 year to 12 year age group, and 53.3% [8/15] in the 13 year to 19 year age group), injection site duration (20.0% [3/15] in the 7 year to 12 year age group), and malaise (20.0% [3/15] in the 13 year to 19 year age group). During the study, no SAEs or AEs that lead to study discontinuation were observed in either group. Conclusion: From these results, it was suggested that additional examination is needed for the 7 year to 12 year age group although two-dose intramuscular administration of KIB-PCI at 3 μg would have sufficient immunogenicity for this group. For the 13 year to 19 year age group, it was suggested that a dose higher than 7.5 μg is needed to give sufficient immunity. There were no significant safety concerns.
Date of Report	October 13, 2016